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ORIGINAL ARTICLE

Comparison of complications associated with standard and totally tubeless percutaneous nephrolithotomy according to modified Clavien grading: A multicenter retrospective study

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Abstract The aim of this study was to compare the complications of standard and totally tubeless percutaneous nephrolithotomy (PCNL) based on the modified Clavien complication grading system. We retrospectively evaluated the complications of 290 consecutive patients who had undergone standard or totally tubeless PCNL at four institutes between January 2010 and August 2012 based on the modified Clavien scale. The totally tubeless cases were classified as Group 1 and the cases to which a Malecot re-entry catheter was applied were classified as Group 2. The postoperative complications were recorded according to the modified Clavien complication grading system. Statistically significant differences were observed only in the first-degree injury class between the two groups based on the modified Clavien classification. The requirement for blood transfusion and prolonged percutaneous access site leakage were more frequent in Group 2, but these differences were not statistically significant. We also performed a pain evaluation by monitoring postoperative analgesia demands. In Group 1, the analgesic demand rates in the 1st and 6th postoperative hours were 64.6% and 31.5%, respectively. In Group 2, the analgesic demand rates were 87.5% and 58.75% in the 1st and 6th postoperative hours, respectively. The mean $\pm$ standard deviation of analgesic doses in the first 6 hours was 0.96 $\pm$ 0.7 and 1.46 $\pm$ 0.6 in Groups 1 and 2, respectively. These differences were statistically significant. Based on our results, we can conclude that the tubeless technique has fewer complications, improved postoperative patient comfort, shorter hospitalization times, and a reduced need for analgesics, suggesting that tubeless PCNL should be the standard

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approach. For suitable cases, this technique may be used safely as the standard PCNL approach.

Introduction

The etiology, treatment modalities, and morbidities of urinary stone disease are highly complex. The prevalence of this condition is increasing in developed countries, and environmental factors, dietary habits, and metabolic abnormalities have gained importance [1]. The European Association of Urology recommended that percutaneous nephrolithotomy (PCNL) should be the primary treatment modality for kidney stones that are larger than 2 cm [2].

The placement of a nephrostomy tube after PCNL treatment is the standard approach. However, totally tubeless PCNL may be feasible in patients who do not require a follow-up treatment or percutaneous chemolitholysis, particularly in the absence of suspected residual stones, potential persistent bacteriuria due to infected stones, significant intraoperative bleeding, urine extravasation or history of ureteral obstruction, solitary kidney, or bleeding diathesis [3—5]. PCNL without a nephrostomy tube or a ureteral catheter is called totally tubeless PCNL—this method has attracted attention in recent years [3,5].

Although the placement of a nephrostomy tube has some advantages such as urinary diversion, hemorrhage control, improved tract recovery, and a tract for secondary operations, the tube may cause pain and early discomfort for the patient [6,7].

Although a recent review has demonstrated that the tubeless method has many advantages, 75% of urologists still prefer to place a tube to avoid complications [8]. To address this dilemma, we performed a retrospective study by re-examining our cases to compare the postoperative comfort and complications of the patients who had undergone PCNL with and without a nephrostomy tube based on the Clavien complication classification scale.

Methods

Patients and study design

In this study, we used the Clavien scale retrospectively to evaluate the complication rates of 290 consecutive patients who had been administered standard or totally tubeless PCNL at four institutes from Ankara, Yozgat and Corum between January 2010 and August 2012. Six specialists who had studied at least 200 PCNL cases were included in the study. The totally tubeless cases were classified as Group 1 and the cases to whom a Malecot re-entry catheter was applied were classified as Group 2. The multi-access cases and the patients with staghorn stones, pyonephrosis, and additional comorbidities were excluded to avoid selection bias. The specialists selected the case groups intraoperatively according to the above-mentioned criteria. The patients were re-evaluated using Kidney, Ureter and Bladder (KUB) graphics and ultrasound (GE logiq S6 - GE Healthcare Wauwatosa, U.S.A.) imaging to identify clinically significant residual fragments, urinomas, or hematomas on the 1st postoperative day.

Routine preoperative evaluation and complete urinary analysis with urine culture were performed for all patients. The patients with a positive urine culture were treated with appropriate antibiotics until they had a negative urine culture. Stone size was calculated as the area of the stone (in mm^2) by multiplying the longest length by the perpendicular length. All the stones were individually measured and their size calculated in the patients with multiple stones. The preoperative and the postoperative hematocrit values were recorded. Thus, the average reduction in the hematocrit values was calculated for the two groups.

Technique

The patients were anesthetized in a supine lithotomy position and a 6F open-ended ureteral catheter was placed in the ureter for retrograde pyelography. The patients were then repositioned in a prone position for access. Access for the collecting system was made via fluoroscopy using an 18 gauge (G) access needle. After the access was made, a guide wire was sent through the calyceal system and dilatation was carried out using Amplatz dilators (Mikrovasive, Natick, MA, USA). A 30 F nephroscope sheath was subsequently placed in the collecting system. The stones were broken into pieces using the appropriate lithotripters after the introduction of the nephroscope into the collecting system. Through—through access was accomplished when the guide wire was seen in the collecting system. Forced expirium was applied to the intercostal accesses also. Hemodynamic parameters and hematocrit values were monitored during the intraoperative and postoperative periods. When a hemodynamic imbalance or an acute decrease in hematocrit level was observed, an erythrocyte transfusion was applied.

The Malecot re-entry catheters were placed into the collecting system until the 2nd postoperative day in the standard group; no catheter was applied postoperatively to the totally tubeless group. However, when urine leakage was observed for longer than 24 hours, a double-J (DJ) catheter was placed. Second-generation cephalosporins were used as prophylactic antibiotics. A body temperature of 38.5°C or above was defined as a significant fever; for these patients, urine and blood cultures were obtained and the antibiotics were changed appropriately according to the antibiogram.

Mean operation and scope times were recorded starting from the time when the first access needle was introduced into the patient in the prone position. The hospitalization

Table 1 Demographic and intraoperative data.

	Group 1 (n = 130)	Group 2 (n = 160)	p
Age (y)	47.3 ± 11.1	51.4 ± 14.3	0.425
Sex (F/M)	56/74	63/97	0.524
Stone burden (mm^2)	289.2 ± 102.4	301.1 ± 169.5	0.713
Average scope time (min)	3.0 ± 1.1	3.1 ± 0.8	0.367
Average operation time (min)	56.6 ± 14.4	59 ± 15.7	0.191
Average decrease in hematocrit (%)	2.9 ± 0.9	3.0 ± 1.2	0.131
Requirement for blood transfusion, n (%)	8 (6.1)	13 (8.1)	0.517

Data are presented as mean ± standard deviation unless otherwise indicated.

time was calculated as the number of days from the operation date to the date of discharge.

Postoperative complications were recorded based on the modified Clavien complication grading system. According to the modified Clavien scale, Grade 1 complications are minor complications that do not require a sophisticated treatment (e.g., analgesic demand or temporary fever). Grade 2 complications require more serious medication than Grade 1 complications such as blood transfusion or parenteral nutrition. Grade 3 complications can be resolved by using radiologic, endoscopic, or surgical interventions; the interventions performed with and without general anesthesia are defined as Grade 3a and Grade 3b, respectively. Grade 4 complications are described as life-threatening ones including central nervous system complications that require an intensive care unit stay; Grade 4a is single organ dysfunction including dialysis, Grade 4b is multiorgan dysfunction. Grade 5 causes death.

The results were described as follows: stone free (SF), clinically insignificant residual fragments (CIRF), and unsuccessful. The stones that were smaller than 4 mm, asymptomatic, noninfective, and nonobstructive were considered as CIRF. Both CIRF and SF cases were considered successful.

Statistical analysis

The SPSS for Windows 16 software package (SPSS, Chicago, IL) was used for data analysis. For nonparametric data, the levels of significant difference observed between the results of the two groups were evaluated using the Chi-square test. The continuous data was evaluated using the independent samples t test method. A p value <0.05 was considered significant.

Results

A total of 290 patients who had undergone PCNL were evaluated. Of these patients, 130 were included in Group 1 and 160 were included in Group 2. The demographics of the two groups were similar. Although the average scope time, hematocrit reduction, operation time, and requirement for blood transfusions were higher in Group 2, these differences were not statistically significant (Table 1).

The average hospital stay was longer in Group 2; the difference was statistically significant. The SF cases were 118 (90.7%) patients in Group 1 and 146 (91.25%) patients in Group 2 (Table 2). In Group 1, prolonged percutaneous access site leakage (i.e., >24 hours) was observed in seven (5.3%) patients; retrograde DJ stent application was performed on these patients. In Group 2, prolonged percutaneous access site leakage was observed in 11 (6.8%) patients after the retrieval of the nephrostomy catheter. In five of these patients, an ipsilateral ureteric stone was seen and treated with the auxiliary ureterorenoscopy. In six patients, the retrograde DJ stent application resolved the leakage. No further complications occurred in any cases. The unsuccessful cases in both groups underwent shock wave lithotripsy.

Statistically significant differences were observed only in the first-degree injury class between the groups in the modified Clavien classification. In Group 2, blood transfusion requirement and prolonged percutaneous access site leakage were more frequent, but these differences were not statistically significant. In the patients who required

Table 2 Hospitalization times and success rates in the study groups.

	Group 1 (n = 130)	Group 2 (n = 160))	p
Duration of hospitalization (d), mean ± SD	1.6 ± 1.1	2.9 ± 1.5	<0.01*
SF rate[a], n (%)	125 (96.1)	151 (94.3)	0.503
Residual fragments[b], n (%)	2 (1.5)	4 (2.5)	0.336
Additional ureteroscopy treatment, n (%)	3 (2.3)	5 (3.1)	0.181
DJ catheter application, n (%)	7 (5.3)	11 (6.8)	0.276

*Statistically significant.
DJ = double-J; SD = standard deviation; SF = stone free.
[a] Including clinically insignificant residual fragments.
[b] >4 mm.

Table 3 Complications graded according to the modified Clavien classification system.

	Group 1 (n = 130)	Group 2 (n = 160)	p
Grade 1, n (%)	85 (65.3)	143 (89.3)	<0.01 *
Postoperative 1st hour analgesic demand	84 (64.6)	140 (87.5)	<0.01
Temporary fever	4 (3.0)	8 (5)	0.414
Temporary increase of creatine	3 (2.3)	5 (3.1)	0.673
Grade 2, n (%)	19 (14.6)	26 (16.3)	0.883
Blood transfusion	8 (6.2)	13 (8.1)	0.519
Urinary leakage	12 (9.2)	16 (10)	0.825
Need to change antibiotic	3 (2.3)	5 (3.1)	0.673
Grade 3, n (%)	9 (6.8)	16 (10)	0.315
Grade 3a (<24 h prolonged urinary leakage)	7 (5.3)	11 (6.8)	0.098
Grade 3b	5 (3.8)	10 (6.2)	0.358
Ureter stone	3 (2.3)	5 (3.1)	0.673
Perirenal hematoma	2 (1.5)	4 (2.5)	0.567
Arteriovenous fistula		1 (0.6)	0.367
Grade 4, n (%)	1 (0.7)	1 (0.6)	0.883
Grade 4a	1 (0.7)	1 (0.6)	0.883
Neighboring organ injury	1 (0.7)	0	0.266
Toxic hepatitis	0	1 (0.6)	0.367
Grade 4b	0	0	
Grade 5, n (%)	0	0	

* Statistically significant.

postoperative analgesia, the pain control was improved by administering 50 mg of diclofenac sodium. In Group 1, the analgesic demand rates in the 1st and 6th postoperative hours were 64.6% (84 patients) and 31.5% (41 patients), respectively. In Group 2, the analgesic demand rates were 87.5% (140 patients) and 58.75% (94 patients) for the 1st and 6th postoperative hours, respectively. The mean number of doses and standard deviation of analgesics in the first 6 hours were 0.96 ± 0.7 and 1.46 ± 0.6 for Groups 1 and 2, respectively. This difference was statistically significant (Table 3).

In Group 1, retroperitoneal colonic injury was observed in one patient; this patient was treated conservatively and did not need surgery. In Group 2, an arteriovenous fistula was observed in one patient; this patient was treated with selective embolization of the segmental artery by the interventional radiology department. In addition, in Group 2, postoperative toxic hepatitis was observed in one patient; this complication resolved spontaneously with conservative treatment.

Discussion

In our study, the group demographics and the success rates were found to be similar. This similarity demonstrated that these groups could be compared. Thus, we examined complication rates and discomfort levels in the context of tube usage after PCNL.

The optimal drainage method applied after PCNL remains unclear although many strategies have been proposed [7,9]. If small nephrostomy tubes were placed, less pain was achieved [10–12]. In addition, less urine leakage was reported following the removal of smaller tubes. No prolonged leakage or urinoma was reported in previous studies [9]. Consistent with this finding, we did not observe such complications in our study either.

PCNL is a difficult operation to perform; even in the most experienced hands, complications may emerge in 1.1–7% of patients. Hemorrhage, which was observed in 1–10% of patients, was the most important complication [13]. Bleeding may occur during needle entry, tract dilatation, and nephroscopy. However, it is usually sufficient to place a nephrostomy tube to avoid this complication. As a result, it may not be possible to achieve hemostasis in patients who undergo tubeless PCNL. In our series, the mean hematocrit loss, blood transfusion rates, and success rates were similar in both groups.

Surgeons usually tend to avoid placing nephrostomy tubes following PCNL—the advantages of this approach include shorter hospital stay, lower pain score, lower need for analgesics, faster return to normal activities, and lower costs.

Another study divided patients randomly into two groups and applied tubeless PCNL to one group and a small diameter (8F) nephrostomy tube to the other, and then compared both groups in terms of pain, requirement for analgesics, and days of hospitalization. A 6F DJ stent was placed in the tubeless group. It was observed that this group had less pain, a lower need for analgesics, and a shorter hospital stay. However, 39.4% of the patients in this group suffered pain from the DJ stent [14]. Based on this finding, we prefer the totally tubeless technique to reduce pain.

In the PCNL series reported by Bdesha et al. [15], all the patients had a mean hospital stay of 2 days and none of the patients required a nephrostomy tube. As a result of growing knowledge and technological advancements, tubeless PCNL has become feasible for patients with complex and staghorn stones [14,16]. Jou et al. [16] evaluated

the results obtained from 64 patients who had undergone tubeless PCNL for stones larger than 3 cm. Of those patients, 14 had staghorn stones. The results demonstrated that tubeless PCNL was safe and effective. Short hospital stays and a reduced need for analgesics were emphasized in that study. Falahatkar et al. compared 42 patients who had undergone tubeless PCNL for staghorn or complex stones with 42 patients who had undergone standard PCNL for staghorn stones [17]. The study reported similar SF rates and complication rates, but the hospital stays were shorter and the need for analgesics was lower for the tubeless PCNL group. In addition, in our study, a significant difference between the hospital stays of the two groups was observed, supporting the advantage of the tubeless PCNL.

In a previous study on large-scale PCNL, Lee et al. [18] reported a major complication rate of 6% (e.g., mortality, sepsis, etc.) and a minor complication rate of >50% (e.g., fever, blood transfusion, urine leakage, etc.) As a result of the technological improvements and advancing experience achieved in the last two decades, complication rates for PCNL have decreased significantly. Tefekli et al. [19] published their PCNL complications according to the modified Clavien scale and their overall complication rate was only 29.2%. Goh and Wolf [20] reported that the overall morbidity rates decreased without tube placement.

The modified Clavien scale is the most common grading system used to report surgical complication rates [21]. In many studies made on standard PCNL, the most common complications were Grades 2 and 3a [17,18,22]. In our study, the standard PCNL group exhibited a significantly higher Grade 1 rate. This difference might have been associated with the discomfort caused by the nephrostomy tube in the 1st postoperative hour; however, this trouble was resolved with the help of analgesics. The other complication rates observed in this study were consistent with those reported in the literature.

In a study published by Karami et al. [12], 210 patients underwent tubeless PCNL. For pain management, diclofenac or indomethacin was used; 50 mg of pethidine was administered to 10 patients. The mean hospital stay was 3.5 days. The researchers concluded that tubeless PCNL was an economical and safe method with high patient comfort [12]. The modified Clavien system is not sufficient for evaluating postoperative pain details because it only measures the intensity and duration of pain. Thus, this system indicates only surgical complications; if a patient was subjected to a postoperative comfort evaluation, further examinations could be required. For this reason, in our study, we also evaluated the analgesic demand and consumption for the 1st and 6th postoperative hours to evaluate the pain duration; the pain duration was also shorter in Group 1.

We routinely use parenteral antibiotics for PCNL surgeries. Because our patients had already been receiving antibiotics, the ones who required an antibiotic change were classified as experiencing Grade 2 complications.

None of the observed Grade 4 complications were related to the use of the tube, but the retroperitoneal colonic injury case served as a reminder that nephrostomy catheters could be helpful for the treatment of colonic injury. We recognized the presence of a colonic injury thanks to some delay in bowel movements and verified our diagnosis via retroperitoneal fluid collection. In this case, we applied a DJ catheter for urine diversion. After stoppage of oral feeding for 5 days, bowel movements restarted and retroperitoneal fluid collection disappeared.

In the current literature, there are few studies comparing standard and totally tubeless PCNL according to the modified Clavien grading. It was also found in our study that the reduced Grade 1 complication rates were related to the need for analgesics. In Group 2, longer hospital stays were necessary due to the presence of the nephrostomy tube.

The decision to close a PCNL operation using the standard or the totally tubeless technique is an intraoperative one. The surgeon must make sure that urine can spontaneously pass through the bladder without any blockage, and the vision through the nephroscope must be clear to prove that the procedure is bloodless.

The major limitation of this article is its retrospective design. Also, multiple surgeons and different centers might have had some effects on the outcomes and the complications due to their heterogeneous clinical attitudes.

Based on our results, we can conclude that the tubeless procedure has fewer complications, improved postoperative patient comfort, shorter hospitalization, and a reduced need for analgesics. These differences might make tubeless PCNL the new standard. In suitable cases, the tubeless procedure can be safely used as the standard for PCNL.

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